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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Nielsen et al.

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Application No.: 10/612,665

Group Art Unit: 1646

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Filed: July 1, 2003

Examiner: To Be Assigned

For:

RECOMBINANT TISSUE

Att

Attorney Docket No.: 10165-022-999

PROTECTIVE CYTOKINES AND ENCODING NUCLEIC ACIDS THEREOF FOR PROTECTION,

RESTORATION, AND

ENHANCEMENT OF RESPONSIVE CELLS, TISSUES, AND ORGANS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.56 AND §1.97

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references A01 to A35, B01 to B08, and C01 to C122 listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant." Copies of references B01 to B08, and C01 to C122 are submitted herewith.

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application.

The Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

This Information Disclosure Statement is being submitted before the mailing date of a first Office Action on the merits; therefore, pursuant to 37 C.F.R. § 1.97(b)(3), no fee is believed due. However, should the Patent and Trademark Office determine otherwise, please charge any required fee to Jones Day Deposit Account No. 50-3013. A duplicate of this sheet is enclosed for accounting purposes.

Respectfully submitted,

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Enclosures

ATTY DOCKET NO. APPLICATION NO
10165-022-999 10/612,665

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(Use several Spects if necessary)

Nielsen, et al.

FILING DATE
July 1, 2003 1646

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	2003/0072737 A1	04/17/03	Brines et al.			
	A02	2003/0040037 A1	02/27/03	Bayer			
	A03	2003/0003529 A1	01/02/03	Bayer			
	A04	2002/0160460 A1	10/31/02	Paulson et al.			
	A05	2002/0142370 A1	10/03/02	Paulson et al.			
	A06	6,489,293	12/3/02	Sytkowski, et al.			
	A07	6,399,336 B1	06/04/02	Paulson et al.			
	A08	6,165,783	12/26/00	Weiss et al.			
1000	A09	6,153,407	11/28/00	Sytkowski, et al.			
	A10	6,071,970	6/6/00	Mueller et al.			
	A11	6,048,971	4/11/00	Sytkowski, et al.			
	A12	5,955,422	9/21/99	Lin			
	A13	5,888,772	3/30/99	Okasinski et al.			
	A14	5,856,298	1/5/99	Strickland			
	A15	5,835,382	11/10/98	Wilson et al.			
	A16	5,830,851	11/3/98	Wrighton et al.			
	A17	5,773,569	6/30/98	Wrighton et al.			
	A18	5,767,078	6/16/98	Johnson et al.			
	A19	5,756,349	5/26/98	Lin			
	A20	5,714,459	2/3/98	O'Brien			
	A21	5,700,909	12/23/97	O'Brien			
	A22	5,696,080	12/9/97	O'Brien			
	A23	5,661,125	8/26/97	Strickland			
	A24	5,625,035	4/29/97	Clemons			
	A25	5,621,080	4/15/97	Lin			
	A26	5,618,698	4/8/97	Lin	771		
	A27	5,614,184	3/25/97	Sytkowski et al.			
	A28	5,604,198	2/18/97	Poduslo et al.			
	A29	5,571,787	11/5/96	O'Brien et al.			
	A30	5,547,933	8/20/96	Lin	5, 1		
	A31	5,457,089	10/10/95	Fibi et al.			
	A32	4,835,260	5/30/89	Shoemaker			
	A33	4,806,524	2/21/89	Kawaguchi et al.			
	A34	4,703,008	10/27/87	Lin			
	A35	4,377,513	3/22/83	Sugimoto et al.			

	FOREIGN PATENT DOCUMENTS							
T	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSL	ATION	
						YES	NO	
В0	5-246885	9/24/93	Japan					
B0	2 WO 01/82953	11/8/01	PCT		,			
В0	3 WO 01/82952	11/8/01	PCT					
ВО	4 WO 00/35475	6/22/00	PCT					
В0	5 WO 98/18926	5/7/98	PCT					
В0	6 WO 97/32895	12/12/97	PCT					
В0	7 WO 97/18318	5/22/97	PCT					
В0	8 WO 95/05465	2/23/95	PCT					

	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
CO	Subarachnoid Hemorrhage," Eur. J. Phar. 406:219-225
C02	Sci. USA 91:3974-3978
C03	Bioassay," Bull. Org. mond. Sante 47:99-112
C04	Glycoproteins," Meth. Enzymol. 50:287-291
C0:	Blood, 98(11, part 2):132b-133b Abstract 4193
CO	Bauer, 1995, "The Oxygen Sensor That Controls EPO Production: Facts and Fancies," J. Perinat. Med., 23:7-12
C0°	Reproduct. 60:861-870
CO	receptor homodimerization." PNAS 100(3):952-957
C09	redox-state of the brain", Glia 30:271-278
Cl	Blood Flow Metab. 19:643-651
CI	Biossel et al., 1993, "Erythropoietin structure-function relationships," J. Biol. Chem. 268(21):15983-15993
CI	Med. 208:337-345
Ci	Briggs et al., 1974, "Hepatic Clearance of Intact and Desialylated Erythropoietin," Am. J. Physiol., 227:1385-1388
Cl-	Brines et al., 2000, "Erythropoietin crosses the blood-brain barrier to -protect against experimental brain injury," Proc Natl. Acad. Sci. USA 97:10526-10531
C1:	Erythrocytosis," Blood, 81:1593-1597
CI	Camiscoli et al., 1968, "Comparative Assay of Erythropoietin Standards," Annals New York Acad. Sci., 149:40-45
C1	Campana et al., 1998, "Identification of a neurotrophic sequence in erythropoietin," Int. J. Mol. Med. 1:235-241
CI	Claus-Walker and Dunn, 1984, "Spinal Cord Injury and Serum Erythropoietin," Arch. Phys. Med. Rehabil., 65:370-374
Ci	Annals New York Acad. Sci., 149:12-17
C2	35:751-760
C2	Reduced Pressure," Nature, 191:1065-1067
C2:	mutagenesis," Science 244(4908):1081-1085
C2.	surface," Nature 415:175-179
C2-	Diright 1 1 1 1 1005 W and in a first in a first in a first in the state of the sta
C2	Di la la 1000 (FDCC) and the latest the latest termination of the late

	treatment," ASAIO J. 38:M477-M480
C26	Dordal et al., 1985, "The Role of Carbohydrate in Erythropoietin Action," Endocrinol., 116:2293-2299
C27	Biological Function," J. Biol. Chem., 263:17516-17521
C28	505
C29	Elliott, et al., 1997, "Mapping of the active site of recombinant human erythropoietin," Blood 89(2):493-502
C30	Eur. Pharmacopoeia, 1997, pp. 5
C31	
C32	Meeting of the American Society of Hematology, Orlando FL, Dec. 7-11, 2001)
C33	73:84-89
C34	of ECVAM Workshop 9, A.T.L.A., 23:699-711
C3:	
C36	
C37	in Erythropoietin Action, J. Biol. Chem., 249:4202-4206
C38	Gorio et al., 2002, "Recombinant human erythropoietin counteracts secondary injury and markedly enhances neurological recovery from experimental spinal cord trauma," Proc. Natl. Acad. Sci. USA 99:9450-9455 (PNAS Early Edition www.pnas.org/cgi/doi/10.1073/pnas.142287899)
C39	Grasso et al., 2002, "Beneficial effects of systemic administration of recombinant human erythrpoietin in rabbits subjected to subarachnoid hemorrhage," Proc. Natl. Acad. Sci. USA 99:5627-5631
C40	expression," Blood 94:87-96
C4:	38:480-486
C42	effects in vivo," JBC 277(81):27581-27584
C4:	Crisis. III. Erythropoietic Effects of Normal Plasma," Erythropoietin, 149:516-527
C44	inhibitor of human primary hematopoietic cell erythropoiesis," Blood, 98(11, part 1):77a Abstract 319
C4:	ID No. 136456, Comp & Dist by NTIS
C40	erythropoietin antagonist," Blood 96(11, part 2):154b Abstract 4366
C4 ⁻	
C48	improves water maze performance in mice," Physiol. Behav. 59:153-156
C49	recombinant human EPO," Am. J. Physiol. 262:F737-F743
C50	Fluid From a Brainstem Hemangioblastoma," Neurology, 41:753-754
C5	194:457-462
C5:	Proc. Natl. Acad. Sci. USA 99:10659-10664 (PNAS Early Edition www.pnas.org/cgi/doi/10.1073/pnas.152321399)
C5:	Soc. for Neuroscience Abstracts 27:929 (31 st Annual Meeting of the Society for Neuroscience, San Diego, CA Nov. 10-15, 2001)
C5-	Early Human Devel. 52:235-249
C5.	Pediatr. Res. 43:40-49
C5	Sci., 149:18-24
C5	Gynecology, 96:826-828
C5	Konishi et al., 1993, "Trophic effect of erythropoietin and other hematopoietic factors on central cholinergic neurons in vitro and in vivo," Brain Res. 609:29-35

C59	mechanism," Behav. Neural Biol. 62:237-243
C60	Latini et al., 1998, "Comparative efficacy of a DA2/α2 agonist and a β-blocker in reducing adrenergic drive and cardiac fibrosis in an experimental model of left ventricular dysfunction after coronary artery occlusion," J. Cardiovasc. Pharmacol. 31:601-608
C61	Li et al., 1998, "A single pre-training glucose injection induces memory facilitation in rodents performing various tasks: contribution of acidic fibroblast growth factor," Neurosci. 85:785-794
C62	I' + 1 1000 "To the relating recentage are supposed in the central new rous system of mid trimector human fatures."
C63	The state of the s
C64	Lipinski et al., 1995, "Nerve growth factor facilitates conditioned taste aversion learning in normal rats," Brain Res. 692:143-153
C65	1: 1 1007 (P. 1111)
C66	T' 1 1000 (4T) and in the second of the language of the property and or the second of
C67	The state of the s
C68	1 1000 "I - tinting of F - the relation by Newsoniaidees and by Mild Substitution Descripes" Natura
C69	1 1000 WE do not be a 100 Tell to the short beautiful to the short b
C70	The state of the s
C71	The state of the s
C72	The state of the s
C73	Masuda et al., 1997, "Insulin-like growth factors and insulin stimulate erythropoietin production in primary cultured astrocytes," Brain Res. 746:63-70
C74	1 1 1004 (th. 1 14 C. 14 14 14 Owner dependent modulation in cultimed not
C75	Masuda et al., 1993, "Functional erythropoietin receptor of the cells with neural characteristics. Comparison with receptor properties of erythroid cells." J. Biol. Chem. 268:11208-11216
C76	t coop (T at a t C at t T at t t T at t t C and a sec 27 I Come
C77	The state of the s
C78	No. 1 1 1000 (FT 1) Compact of the state of
C79	1.61 - 1.00 - 10 - 10 - 10 - 10 - 10 - 10 -
C80	Morishita et al., 1997, "Erythropoietin receptor is expressed in rat hippocampal and cerebral cortical neurons, and erythropoietin prevents <i>in vitro</i> glutamate-induced neuronal death," Neurosci. 76:105-116
C8:	The state of the s
C82	15 1 1 1000 60 desiries estados maneros formacion in hoolthy young adulto "
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C88	Ot 1 1 1000 (FT 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
C89	Page et al., 1996, "A sensitive human cell line based bioassay for megakaryocyte growth and development factor or
	thrombopoietin," Cytokine 8(1):66-69 Pardridge, 1997, "Drug delivery to the brain," J. Cerebral Blood Flow Metab. 17:713-731
C90	

C92	Park et al., 1997, "Development of an in vitro bioassay system for human thrombopoietin by constructing a recombinant murine cell line expressing human thrombopoietin receptor," Mol. Cells. 7(6):699-704
C93	Peng et al., 2000, "HPLC/ESI MS and MALDI/TOF MS analysis of microheterogeneity of the N-linked oligosaccharides of recombinant human erythropoietin," Yao Xue Xue Bao (Acta Pharmaceutica Sinica) 35(10):764-769 Chinese
C94	Poduslo et al., 1994, "Macromolecular premeability across the blood-nerve and blood-brain barriers," Proc. Natl. Acad. Sci. USA 91:5705-5709
C95	Prendergast et al., 1997, "Nitric oxide synthase inhibition impairs spatial navigation learning and induces conditioned taste aversion," Pharmacol. Biochem. Behav. 57:347-352
C96	Qiu et al., 1998, "Homodimerization restores biological activity to an inactive erythropoietin mutant," J. Biol. Chem. 273(18):11173-11176
C97	Rose and Audus, 1998, "Receptor-mediated angiotensin II transcytosis by brain microvessel endothelial cells," Peptides 19:1023-1030
C98	Rush et al., 1995, "Microheterogeneity of erythropoietin carbohydrate structure," Analytical Chemistry, 67(8):1442-1452
C99	Rush et al., 1993, "Peptide mapping and evaluation of glycopeptide microheterogeneity derived from endoproteinase
C99	digestion of erythropoietin by affinity high-performance capillary electrophoresis," Anal. Chem. 65(14):1834-1842
C100	Sadamoto et al., 1998, "Erythropoietin prevents place navigation disability and cortical infarction in rats with permanent occlusion of the middle cerebral artery," Biochem. Biophys. Res. Comm. 253:26-32
C101	Sakanaka et al., 1998, "In vivo evidence that erythropoietin protects neurons from ischemic damage," Proc. Natl. Acad. Sci. USA 95:4635-4640
C102	Satake et al., 1990 "Chemical modification of erythropoietin: an increase in <i>in vitro</i> activity by guanidination," Biochim. Biophys Acta. 1038(1):125-129
C103	Sawyer et al., 1989, "Receptors for erythropoietin in mouse and human erythroid cells and placenta," Blood 74:103-109
C104	Shiramizu et al., 1994, "Constitutive Secretion of Erythropoietin by Human Renal Adenocarcinoma Cells in Vivo and in Vitro," Exp. Cell Res., 215:249-256
C105	Shore et al., 1968, "Quantitative Estimation of Erythropoietin," Annals New York Acad. Sci., 149:46-48
C106	Silva et al., 1999, "Erythropoietin can induce the expression of bcl-x _L through Stat5 in erythropoietin-dependent progenitor cell lines," J. Biol. Chem. 274:22165-22169
C107	Sirén et al., 2001, "Erythropoietin prevents neuronal apoptosis after cerebral ischemia and metabolic stress," Proc. Natl. Acad. Sci. USA 98:4044-4049
C108	Spivak and Hogans, 1989, "The In Vivo Metabolism of Recombinant Human Erythropoietin in the Rat," Blood 73:90-
C109	Storring et al., 1998, "Epoietin Alfa and Beta Differ In Erythropoietin Isoform Compositions and Biological Properties," British J. Haematology, 100:79-89
C110	Storring and Gaines Das, 1992, "The International Standard for Recombinant DNA-Derived Erythropoietin: Collaborative Study of Four Recombinant DNA-derived Erythropoietins and Two Highly Purified Human Urinary Erythropoietins," <i>J. Endocrinol.</i> , 134 :459-484.
C111	Suzuki et al., 2001, "Erythropoietin Synthesis by Tumour Tissues in a Patient With Uterine Myoma and ERythrocytosis," British J. Haematology, 113:49-51.
C112	Syed et al., 1998, "Efficiency of signalling through cytokine receptors depends critically on receptor orientation,"
C113	Nature 395:511-516 Tabira et al., 1995, "Neurotrophic effect of hematopoietic cytokines on cholinergic and other neurons <i>in vitro</i> ", Int. J. Devl. Neurosci. 13:241-252
C114	The state of the s
C115	Wen et al., 1994, "erythropoietin structure-function relationships," J. Biol. Chem. 269(36):22839-22846
C116	W. Cil. 1 1000 WY
C117	Williams et al., 1994, "Human erythropoietin receptor", Ann. NY Acad. Sci. 718:232-244
C118	Wojchowski et al., 1989, "Biotinylated recombinant human erythropoietins: Bioactivity and utility as receptor ligand," Blood 74(3):952-958
C119	Wolcott et al., 1989, "Recombinant human erythropoietin treatment may improve quality of life and cognitive function in chronic hemodialysis patients", Am. J. Kidney Dis. 14:478-485
C120	TTT 10 1 1007 WT 11 11 11 11 11 11 11 11 11 11 11 11 11
C121	Wu and Pardridge, 1999, "Neuroprotection with noninvasive neurotrophin delivery to the brain", Neurobiol. 96 :254-259
	Yamaji et al., 1996, "Brain capillary endothelial cells express two forms of erythropoietin receptor mRNA", Eur. J.

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.